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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,202	12/01/2003	Richard M. Batch	61616	3293

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EXAMINER	
HOPKINS, CHRISTINE D	
ART UNIT	**PAPER NUMBER**
3735	

MAIL DATE	DELIVERY MODE
06/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/726,202	BATCH, RICHARD M.	
	Examiner	Art Unit	
	Christine D. Hopkins	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1 JUNE 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-17 and 19-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-17 and 19-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7 Feb 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1 June 2007 has been entered. The Examiner acknowledges the amendments to claims 1 and 11-12, as well as the addition of claims 21-23.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-6, 8-17 and 19-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Bocionek et al. (U.S. Pub. No. 2002/0099273). Bocionek et al. (hereinafter Bocionek) disclose a medical information system which retains and processes information from various sources for use in clinical care delivery. Regarding claims 1, 3, 8-9 and 22, Bocionek teaches a system for analyzing medical treatment data associated with medical treatment from a plurality of patients to determine a treatment guideline based on treatment administered to a plurality of patients, and for updating at least one medical device (infusion pump **85**) with the guideline ([0020],

[0027], [0030]). Database **75** stores medical treatment data associated with medical treatments delivered to a plurality of patients; the medical treatment data including a plurality of treatment parameters for each of the plurality of patients and a treatment parameter value associated with each treatment parameter such as vital signs, drug interactions and patient organ images ([0018], [0020], [0024], [0028], [0029]). A processor connected to the database is configured to compile from the medical treatment data a plurality of treatment parameter values associated with a selected treatment parameter, analyze the values and determine a treatment guideline representing acceptable values for the selected parameter, such as potential drug interactions [0022]. Decision functions **15** and **17** automatically supply a medical device such as an infusion pump with an optimized drug dosage [0027]. With further reference to claim 3, database **77** stores preestablished medical treatment guidelines [0020].

Regarding claims 2 and 4, a statistical distribution is provided by the analysis of the complied treatment parameters as evidenced by alarm function **27**, serving as a function of optimized thresholds. Decision support functions **15** and **17** determine new or improved treatment solutions, thus adjusting acceptable values for the selected treatment parameter in the preestablished guidelines [0027]. A message based on a particular analysis may be displaced to a user on a monitor or an interface display [0035], thus generating a report of the analysis or comparison in accordance with claims 5 and 6.

With respect to claim 10, the medical treatment data may include patient physiological data such as vital signs. Decision support functions derive conclusions

based on the vital signs and available patient data and parameters to optimize settings and thresholds ([0026]-[0027]).

Regarding claim 11, Bocionek teaches a plurality of medication administration devices **81-87** for multiple patients, each associated with data acquired from a patient including patient identification, medication and operating parameters. A central processor **19**, **21** is configured to receive medical treatment data from the administration devices and a database **77** operatively connected to the processor stores preestablished medical treatment guidelines representing acceptable values for the medical administration device operating parameters. Interface **90** interconnects medical devices within a patient's room to the central processor. The processor is further configured to compile a plurality of parameter values associated with a selected device operating parameter, analyzed the values and determine a medical treatment guideline based on the analysis representing acceptable values ([0016], [0017], [0028]).

Referring to claim 12, Bocionek teaches a method of communicating medical treatment data associated with medical treatments delivered to a plurality of patients, the treatment data including a plurality of treatment parameters for each of the plurality of patients and a treatment parameter value associated with each parameter; compiling from the treatment data a plurality of parameter values associated with a selected parameter; analyzing the complied treatment parameter values, determining an optimal treatment guideline based on the analysis and providing the optimized guideline to an infusion pump from a remote location ([0018], [0020], [0024], [0027]-[0030]). Regarding claim 13, a statistical distribution is provided by the analysis of the complied treatment

parameters as evidenced by alarm function **27**, serving as a function of optimized thresholds.

With reference to claim 14, database **77** stores preestablished medical treatment guidelines [0020]. Decision functions **15** and **17** compare compiled treatment parameter values such as from patient monitoring devices to the acceptable values for a treatment parameter retrieved from preestablished medical treatment guidelines in database **77** [0024]. The decision functions determine new and improved treatment solutions which are substituted for the existing solutions in database **77**, thus creating an updated medical treatment guideline [0026], in accordance with claim 15. A message based on a particular analysis may be displaced to a user on a monitor or an interface display [0035], thus generating a report of the analysis or comparison in accordance with claims 16 and 17.

Regarding claims 19-21, database **77** is dynamically updated to incorporate improved treatments and their associated medical outcome results [0020]. A processor connected to the database compiles from the medical treatment data a plurality of treatment parameter values associated with a selected treatment parameter, analyzes the values and determines a treatment guideline representing acceptable values for the selected parameter, such as potential drug interactions [0022].

With respect to claim 23, Bocionek teaches a system for analyzing medical treatment data associated with medical treatment from a plurality of patients to determine a treatment guideline based on treatment administered to a plurality of patients, and for updating at least one medical device (infusion pump **85**) with the

guideline ([0020], [0027], [0030]). Database **75** stores medical treatment data associated with medical treatments delivered to a plurality of patients; the medical treatment data including a plurality of treatment parameters for each of the plurality of patients and a treatment parameter value associated with each treatment parameter such as vital signs, drug interactions and patient organ images ([0018], [0020], [0024], [0028], [0029]). A processor connected to the database is configured to compile from the medical treatment data a plurality of treatment parameter values associated with a selected treatment parameter, analyze the values and determine a treatment guideline representing acceptable values for the selected parameter, such as potential drug interactions [0022]. Decision functions **15** and **17** automatically supply a medical device such as an infusion pump with an optimized drug dosage [0027]. Alarm function **29** generates an alarm based on vital signs collected from patient monitoring units. Decision support functions derive conclusions based on medical data and patient vital signs and parameters and optimize the alarm function settings and thresholds [0026].

Response to Arguments

4. Applicant's arguments filed 1 June 2007 with respect to the objection to claim 11 have been fully considered and are persuasive. The objection to claim 11 has been withdrawn.

5. Applicant's arguments with respect to claims 1-6, 8-10, 12-17 and 19-20 under 35 U.S.C. 102(b) citing McIlroy ('758) have been fully considered but are moot in view of the new grounds of rejection citing Bocionek (U.S. Pub. No. 2002/0099273).

6. Applicant's arguments with respect to claim 11 under 35 U.S.C. 102(b) citing Coutre ('506) have been fully considered but are moot in view of the new grounds of rejection citing Bocionek (U.S. Pub. No. 2002/0099273).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christine D Hopkins
Examiner
Art Unit 3735

Charles A. Marmor, II
Supervisory Patent Examiner
Art Unit 3735